Annexure 3

MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

Code of Conduct

Edition 14
Guidelines

Version 1: 20 December 2002

Effective from 1 January, 2003

Index

Introduction

These Guidelines have been written to provide assistance to companies in complying with the provisions of the Medicines Australia Code of Conduct. The Guidelines provide insight both into the experiences of the Code of Conduct and Monitoring Committees and the deliberations of Medicines Australia and its members when developing amendments to the Code of Conduct.

These Guidelines are a living document and will be augmented as issues arise or where requested by the Code of Conduct Committee or the Medicines Australia membership.

In addition to these Guidelines, the Code, through its Explanatory Notes, provides assistance on understanding the Code and compliance with the Code.

These Guidelines do not cover all sections of the Code. However, if you would like any further assistance regarding the Code, its interpretation or operation, please contact Medicines Australia on (02) 6282 6888.

To gain a first hand experience of how the Committee considers the sections of the Code, companies are encouraged to accept when offered invitations to attend Code of Conduct meetings as either Committee members or observers.

Format

The format of these Guidelines is to present the text of the Section and its Explanatory Notes (in italics), then to provide guidance as to the section's interpretation and compliance with the section.

For convenience, the Sections dealing with PBS information disclosure have been grouped together. They set out the requirements for the provision of this information in various media.

Section 1.2 – Substantiating Data

Section

1.2 ***Substantiating Data***

1.2.1 ***Provision of Substantiating Data***
Further to the information supplied or generally available, a company will, upon reasonable request, provide healthcare professionals with additional accurate and relevant information about products which it markets, including company information.

Data in support of a claim, including "data on file" or "in press" must be made available without delay upon reasonable request.

Where this material is not available through standard library services, it must be made available without delay.

1.2.2 ***Level of Substantiating Data***
Any information used to support a medical or promotional claim must include sufficient detail and be of adequate quality to allow evaluation of the validity of results and hence the claim.

Such substantiating information must not rely ***solely*** *on data on file.*

Explanatory Notes

1.2.1 *(a) All data to substantiate claims must be easily retrievable so that they could be supplied on request within 10 working days.*

(b) Evaluated data contained in an application for marketing in accordance with the current or previous Therapeutic Goods Administration guidelines for the registration of products may be used to substantiate claims. Such data must be made available when requested to substantiate a claim. A statement that the data are "Confidential" will not be accepted.*

(c) If the information on which a claim is based may not be released, eg an "in press" article which is subject to confidentiality provisions, then that information may not be used to substantiate a claim for the purposes of satisfying this section. Papers cited as "in press" must have been accepted for publication and be available as a final approved manuscript or in proof form. Papers submitted for publication and not yet accepted by a journal may be identified only as "unpublished data", "personal communication", "unrefereed data" or in similar terms.

(d) Data relating to the cost effectiveness of a product may be used to substantiate promotional claims, however these data must conform with Sections 1.1, 1.2, 1.3, 1.5 and 1.7 of this Code.

1.2.2 *In determining whether sufficient evidence is available to support a claim, companies should have regard to issues such as, but not limited to, the study design, the number of patients, the location of any trial or study, its primary purpose and end points, the results, the reputation and qualifications of the people involved*

in the study or trial, its consistency in the current body of evidence and where (eg peer reviewed journal or pay journal) or if it has been published.

For example, to satisfy the requirements of this section the evidence to support any major claim that will have a significant impact on the prescribing of a product, must be unequivocal and the highest quality. It should not rely upon evidence from sources such as poster presentations or abstracts that do not provide sufficient information to assess the veracity of the claim. Used appropriately these information sources may be used to support lesser or minor claims.

For further guidance regarding the application of this section please refer to the current Guidelines to the Code of Conduct.

Guidelines

The purpose of this section is twofold. First, to ensure that supporting evidence can be made available to both health care professionals and members of the industry in a timely manner. The section requires that supporting data must be made available upon reasonable request to both health care professionals and members of the industry. It is suggested, in the majority of cases, the provision of this data should take place within ten working days of the request. The provision of this material includes any "data on file" or "in press" material that a company may reference in support of claims which must be provided to health care professionals and members of the industry upon reasonable request.

Companies should be aware that by referencing "data on file" or "in press" material it is possible that a request may be made for it which must be honoured under the requirements of this section.

The second requirement of the section relates to the level of substantiating data needed to support medical or promotional claims. Note that these provisions are in addition to those of Section 1.1, which requires that all medical and promotional claims are fully supported by the Product Information, literature, data on file or appropriate industry source where the last do not conflict with the Product Information.

The Explanatory Notes to this Section describe the types of issues to which companies should look when assessing whether the evidence they have is sufficient to meet the requirements of this Section.

The Code of Conduct Committee, when it considers complaints against medical or promotional claims, uses a hierarchy of evidence to determine whether the substantiating data provided meets the requirements of this section.

Useful guides to understanding this hierarchy of evidence are two NHMRC publications entitled "A guide to the development, implementation and evaluation of clinical practice guidelines" and "How to use the evidence assessment and application of scientific evidence". These guidelines describe levels of evidence ranging from

Level 1 evidence (obtained from a systematic review of all relevant randomised controlled trials) to Level IV evidence (obtained from case series, either post-test or pre-test/post-test). The Committee uses the principles in these documents to determine the quality of the evidence provided to it in support of medical and promotional claims made.

The Code of Conduct Committee considers that claims which will significantly influence how a medicine is prescribed or dispensed should be supported by the highest level of evidence available. For example, a major comparative claim stating that one product is more efficacious than another must be supported by evidence that would not leave the reader in any doubt regarding the superiority of the product. The quality of the data to support this claim is therefore critical to ensure that readers can be assured that such claims are based on appropriate evidence.

Comparative advertising must always meet all the requirements of the Code set out in Sections 1.3 and 1.7.

For the reasons given above, the Committee considers that in general, abstracts and poster presentations that have not undergone significant peer review and/or have not been accepted for publication in recognised major journals are insufficient as a base for major promotional claims. This does not mean that these data sources cannot be used at all. However, in general, they cannot be relied on as the sole support for major claims which will have a significant influence on how a medicine is prescribed or dispensed.

As the Explanatory Notes to this Section describe, companies should look to issues such as:-

- the study design
- the number of patients
- the location of the study
- its primary purpose and end points
- the results
- the reputation and qualifications of the trialists
- the studies place within the current body of evidence, and
- whether and where the results from the study have been published

when assessing whether the evidence they have is sufficient to meet the requirements of this Section.

The Code of Conduct Committee also has a preference for being told when a company has made a financial contribution to a study which is relied on as substantiating data.

The Code of Conduct Committee, when considering a complaint, requires that any substantiating data is provided to it and will rigorously review this data to ensure that it is of sufficient quality and weight to support the claims being made. The addition of a permanent member of ASCEPT and the other health care professionals on the Code of Conduct Committee greatly assists the Committee in its determination on whether the evidence provided is sufficient to support the claims made.

The Committee will not find any substantiating data itself in breach of the Code. Rather, a breach may be found through inappropriate reliance on certain substantiating data.

Section 1.3 False and Misleading Claims

Section

1.3 ***False or Misleading Claims***
All information, claims and graphical representations provided to health care professionals and members of the general public must be current, accurate, balanced and must not mislead either directly, by implication, or by omission.

Claims must be referenced where there is a possibility that a reader may be misled if the source of the reference is not disclosed.

1.3.1 ***Unapproved products and indications***
Products that have not been approved for registration by the Department of Health and Ageing must not be promoted. However, samples of unapproved products may be displayed and educational material made available at International Congresses* and Australasian Congresses in accordance with Section 6. This restriction also applies to unapproved indications for registered products.*

Explanatory Notes

1.3 *The majority of breaches of the Code found concern this section. The following are examples of situations where material may breach the Code. This list is not all inclusive and is based on the experience of the Code of Conduct Committee.*

(a) Literature references or quotations derived from a study or studies and citations of individual opinions which are significantly more favourable or unfavourable than has been demonstrated either within the study, or more likely from the body of clinical evidence or experience. It is unreasonable to cite the results of an excessively favourable (or excessively unfavourable to a comparative product) study in a manner which misleadingly suggests that those results are typical.

(b) Information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions.

(c) Citation of data previously valid but made obsolete or false by the evaluation of new data.

(d) Suggestions or representations of uses, dosages, indications or any other aspect of the Product Information not approved by the Commonwealth Department of Health and Ageing.

(e) Shortening an approved indication (eg in a by-line) so as to remove a qualification or limitation to the indication.

(f) Use of animal or laboratory data as sole evidence to support a promotional claim. It should be noted that if animal or laboratory data are used a prominent statement identifying this type of data and acknowledging that such data does not necessarily predict clinical effects must be made on the same page and within reasonable proximity to the data in a manner that is not obscured by other material.

(g) Presentation of information in such a manner eg type size and layout, which, to the casual reader could produce an incorrect perspective. The type size used for*

qualifying statements must not be less than 2mm. The qualifying statement must not be included with other reference material but must be situated on the same page as the original statement. The original statement and the qualifying statement must be linked by use of a readily identifiable asterisk or a similar symbol.

(h) Statements made about a competitive product, particularly negative statements, not balanced with corresponding information about the product being promoted.

(i) Shortening the title of graphical representations reproduced from literature which alters the original author's meaning.

(j) Use of overseas Product Information to support a claim where that information is inconsistent with the Australian Approved Product Information.

(k) Literal or implied claims that a parameter, - contraindication, cautionary statement, adverse reaction or limitation on a claim in the Product Information, is not cause for concern.

(l) Lack of substantiation of claims not of a medical or scientific nature. It includes information or claims relating to marketing factors such as pricing and market share. Care should be taken when extrapolating prescribing practices from sales data.

1.3.1 *Where a company has been formally advised by the Department of Health and Ageing that a product has been approved and its Product Information has been finalised, it is considered approved for registration for the purpose of this Code.*

Guidelines

The purpose of this section of the Code is to ensure that claims and statements made by the industry are current, accurate, balanced and not misleading.

The section relates not only to promotional and medical claims, but to all information and graphical representations provided both to health care professionals and members of the general public. This includes tag lines in promotional material provided to health care professionals.

To ensure that all material complies with this section, the following tests should be applied. All information provided to health care professionals and members of the general public must be:-

- Current
- Accurate
- Balanced, and
- Must not mislead, either directly, by implication or by omission.

The Explanatory Notes to this section provide significant guidance on how companies can comply with this section. However, the following may provide further assistance.

When comparative claims are made, the Code of Conduct Committee, require unequivocal evidence that the comparison meets the requirements of this section. Care should therefore be taken to ensure that any comparative claims are both supported by appropriate evidence and are reported accurately. Given the possible significant impact of comparative claims on prescribing practices, the Code requires a higher level of evidence to support such claims. See also Section 1.7 – Comparative Statements.

Care should also be taken when using animal data (Explanatory Note (f)). The Code requires that if animal or laboratory data is being used it is clearly identified. In the past, use of a small asterix or symbol that refers to statements in small font sizes has been found inadequate and to have breached the Code. The Code of Conduct Committee prefers to see such statements adjacent to the animal or laboratory claim or data and in a sufficient size (not less than 2 mm) to ensure that the reader is aware of the source of this claim or data. Care should also be taken to ensure that when using this data that there is no inference, either intentionally or by omission, that would lead a reader to infer some clinical effect. Again, a prominently worded statement to this effect would be beneficial.

The Explanatory Note to Section 1.3 (f) should not be read as prohibiting the use of animal or laboratory data as substantiation for claims that cannot be proven by any other mechanism. These characteristics, with any limitations, would also be reflected in the approved Product Information for these products.

Companies should note that this section and Sections 1.1 and 1.2 also cover tag lines, although in some instances the Committee will accept that some tag lines are just promotional puffery and will not have a real impact upon health care professionals. The test will be whether the tag line makes an implicit or inferred claim and, if it does, whether there is sufficient evidence to support such a claim.

In relation to the currency of substantiating data, it should be noted that companies may use data to support claims that is not included in a product's Product Information. However this data must not conflict with the Product Information. The Code of Conduct Committee expects that where there is new evidence about a product that may not be consistent with its Product Information, this data should not be used to support promotional claims. The Committee would expect that a company would update its Product Information to reflect this new data which could then be relied on for promotional purposes.

Section 1.7 – Comparative Statements

Section

1.7 ***Comparative Statements***

Comparison of products must not be disparaging, but must be factual, fair and capable of substantiation and referenced to its source. In presenting a comparison, care must be taken to ensure that it properly reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way. "Hanging" comparatives - those which merely claim that a product is better, stronger, more widely prescribed etc must not be used.

"Data on file" when used to substantiate comparative statements must comply with the requirement of Section 1.2.

Explanatory Notes

1.7 *Pharmaceutical advertising commonly contains comparisons with other products and such comparisons are usually made to show an advantage of the advertised product over its competitor(s). Provided that such comparisons with other products are factual, fair and can be substantiated, they are acceptable under the Code.*

The intention of this clause is to prohibit unfair and unjustified comparisons with the products or activities of a competitor.

Where a claim of comparative efficacy or safety is made, it must not be based solely on a comparison of Product Information documents that does not reflect the general literature, as those documents are based on different databases and are not directly comparable. This applies to Australian as well as overseas Product Information documents.

Claims of comparative efficacy or safety should be substantiated with respect to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter.

The accepted level of statistical significance is $p < 0.05$. If comparative data that are not statistically significant are used, such data must comply with the following conditions:

- *the lack of significance must be stated explicitly; it is insufficient to state the p value*
- *the data must not be used to generalise or to indicate superiority or inferiority*

The statement that the claim is not statistically significant needs to be linked in some manner to the original claim, made on the same page and within a reasonable proximity of the original claim in a manner that is not obscured by other material using a type size of not less than 2mm.

Care should be taken to distinguish between mathematically determined statistical significance on the one hand and clinical significance on the other.

Guidelines

The intention of this provision is to prohibit unjustified comparisons in which the product or activities of a competitor are unfairly denigrated.

It is important to remember that if you are making comparative claims you need unequivocal supporting evidence. If a comparative claim comes before the Code Committee it will carefully scrutinise the evidence provided to ensure it is sufficient to support the comparison being made. This will include a review of the type of evidence provided, for example, an examination of issues such as the protocols of any studies relied on, the primary and secondary results of these studies, the authors, and if/where the study was published (see also Section 1.2 for further information on supporting evidence).

The intent of any comparison should be that it provides valuable and accurate information comparing products for the benefit of health care professionals and their patients. Care should also, therefore, be taken in the way a comparative claim is presented. It is critical that the depiction of any comparison is accurate. Care should be taken, for example, to ensure that any graphical or visual comparisons between products are accurate and appropriate.

For example, a breach of the Code has been found by the use of unequal width bars in a bar graph comparing the efficacy of two products, which inferred that the results of the comparison were more meaningful for one product than another. Such a graph was considered unfair and misleading and found to be in breach of Section 1.7.

PBS Disclosure Requirements

Background

In the lead up to the 2002 Federal Budget, Medicines Australia discussed with the government ways in which PBS expenditure could be reduced by ensuring prescribers were provided with information regarding the PBS status of medicines. In an effort to assist the government, Medicines Australia agreed to make amendments to its Code of Conduct to require the disclosure of this information in promotional material and by its medical representatives. The amendments to the Code adopted in September 2002 reflect this agreement with government.

The following discussion sets out the requirements of how this information should be disclosed.

Section 3.1.1 Primary Advertisements

This section requires that various promotional materials include a clear and prominent statement drawing the attention of the reader to any Pharmaceutical Benefits Scheme (PBS) listing and restriction. The following guidelines identify the minimum requirements for the content and layout of this disclosure in promotional material.

1. General Requirements:-

These requirements apply to advertisements and printed promotional material:-

1. The PBS disclosure information should be contained with a text box that has a white background and is outlined in black.
2. The font used should be either Arial or Universal (not condensed forms) or a similar clear "sans" face. (NB fonts corresponding to these may go under different names, e.g. Helvetica.)
3. The text should appear in solid black with no half tones.
4. The spacing within the text box must make conventional use of upper and lower case type and contain adequate space between any lines and words to ensure easy readability.
5. The text size must be the largest that can be contained in the text box and in some material should not be less than 2mm.
6. The text box must contain only the PBS disclosure information. No embellishments or other material should be included in this box.

2. Wording

1. For products listed on the PBS without any restrictions, the following wording should appear in the text box: "PBS Information: This product(s) is listed on the PBS as a *(insert the product type of product as identified in the Schedule)*".

e.g.: **PBS Information: This product is listed on the PBS as a drug for obstructive airway diseases**

2. For products listed on the PBS as a restricted benefit or where an authority is required, and this information is no longer than three lines as they appear in the PBS Schedule, the following wording should appear in the text box: "PBS Information: Restricted Benefit *or* Authority Required. *Insert wording of the restriction or authority requirement*".

e.g. **PBS Information: Restricted benefit. Symptomatic treatment of osteoarthritis**

3. For products listed on the PBS as a restricted benefit or where an authority is required, and this information is longer than three lines as they appear in the PBS Schedule, the following wording should appear in the text box: "PBS Information: Restricted Benefit *or* Authority Required. *Either the statement* "Refer to PBS Schedule for full information" *or an accurate paraphrase or precis of the PBS restriction*".

e.g. **PBS Information: Restricted benefit. Refer to PBS Schedule for full restricted benefit information.**

e.g. **PBS Information: Restricted benefit. For use in patients that meet the criteria set out in the General Statement for Lipid Lowering Drugs**

4. For products not listed on the PBS, the following wording should appear in the text box: "PBS Information: This product(s) is not listed on the PBS".

e.g.: **PBS Information: This product is not listed on the PBS.**

3. Size

Primary Advertisements

1. Full or double Page advertisements (such as appear in medical journals e.g. Australian Doctor or Medical Observer) or advertisements of A4 size or greater.

The text box must be no smaller than 18 cm^2 and must allow text of no smaller than 2mm. For example, a text box could measure 12cm x 1.5cm, 6cm x 3cm, 18cm x 1 cm or 9cm x 2cm.

The size of the text will depend upon the length of the disclosure statement and the size of the text box, but must not be less than 2 mm as measured by the font's letter "e".

2. Half page advertisements (such as appear in medical journals e.g. Australian Doctor or Medical Observer) or advertisements of size A5 up to A4

   The text box must be no smaller than 15 cm^2 and must allow text of no smaller than 2mm. For example, a text box could measure 15cm x 1cm, 5cm x 3cm, 7.5cm x 2 cm or 10cm x 1.5cm.

   The size of the text will depend upon the length of the disclosure statement and the size of the text box, but must not be less than 2 mm as measured by the font's letter "e".

3. Quarter page advertisements (such as appear in medical journals e.g. Australian Doctor or Medical Observer) or advertisements less than A5 size

   The text box must be no smaller than 10 cm^2 and must allow text of no smaller than 2mm. For example, a text box could measure 10cm x 1cm, 5cm x 2cm, 7.5cm x 1.33 cm or 8cm x 1.25cm.

   The size of the text will depend upon the length of the disclosure statement and the size of the text box, but must not be less than 2 mm as measured by the font's letter "e".

Secondary and Short Advertisements

If a secondary or a short advertisement appears by itself within one publication, the size requirements relating to primary advertisements apply. If a secondary or short advertisement appears in a publication in which a primary advertisement for the same product also appears, the following text must appear in the secondary or short advertisement in a type size of not less than 2mm "For PBS information refer to primary advertisement".

Reference Manual Advertising

For all reference manual advertising which is greater than a third of a page as measured by the Reference Manual, a text box must appear containing the statement "For PBS Information refer to Section *insert relevant reference manual*

section". The size of the font must be not less than 2mm measured by the font's letter "e".

e.g.: **For PBS Information refer to Section 2(f)**

For advertising which is less than a third of a page, companies are encouraged to include a statement advising health care professionals of the location of the PBS information within the Reference Manual.

Printed Promotional Material (Section 3.3.1)

The size requirements applying to full advertisements also apply to printed promotional material and text which complies with these requirements should appear at least once in each item of printed promotional material.

Audiovisual Promotional Material (Section 3.3.2)
Computer Based Promotional Material (Section 3.3.5)
Television Advertising (Section 3.4)

All PBS listing information as required in the general requirements must be displayed in these promotional media in a manner that allows the audience to read and understand the information provided. The type size used in these media must be such that allows easy and clear legibility and should be contained in a text box that commences with the statement "PBS information".

Medical Representatives (Section 4.8)

This section of the Code requires that medical representatives either provide prescribers with information regarding all PBS listings and restrictions, or make reference to this material in printed form when they are making promotional claims regarding a prescription product. It is sufficient for a medical representative to verbally advise a health care professional of this information, to provide them with this information in written form or to refer to a printed source of this information.

The disclosure should be clear and distinct with no attempt to minimize or limit this important information.

Section 3.3.3 - Brand name reminders

Section

3.3.3.1 *Brand Name Reminders must include the following information:*

(a) The brand name of the product

(b) The Australian Approved Name(s) of the active ingredient(s)

(c) Where applicable, the notation "See Warning" or "See Boxed Warning" drawing attention to the boxed warning in the Product Information.

Brand Name Reminders may also include:-

(d) a non-promotional logo, device or graph

(e) a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the product

3.3.3.2 *Brand Name Reminders are not to contain any promotional claims including promotional tag lines and or statements.*

3.3.3.3 *Brand Name Reminders will only be acceptable if it is possible to clearly and legibly display the product's brand name. Where the nature of a Brand Name Reminder is such that it is demonstrably and obviously impractical to display the Australian Approved Name(s) of the active ingredient(s) as required in Section 3.3.3.1, the Brand Name Reminder must be accompanied by a document containing the information specified in Section 3.3.3.1.*

3.3.3.4 *Where the nature of a Brand Name Reminder is such that it is demonstrably and obviously impractical to display legibly the notation "See Warning" or "See Boxed Warning" as required in Section 3.3.3.1, a Brand Name Reminder must not be used for that product.*

Explanatory Notes

3.3.3 *An individual Brand Name Reminder should only be of token value, should not bring discredit to the industry and should be chosen on the basis that the item is clearly a Brand Name Reminder and not any other promotional material such as printed promotional material. The nature of any Brand Name Reminder or its packaging must not have the capacity to be confused with a therapeutic good.*

3.3.3.1 *(b) The Australian Approved Name should appear adjacent to the most prominent presentation of the trade name.*

Guidelines

A brand name reminder is an item of low monetary value which is intended to remind health care professionals of the existence of a product. Items such as mugs, pens, mouse pads and boxes of tissues are examples of acceptable brand name reminders.

When choosing items to be used as brand name reminders, it is important that the items can clearly be recognised as a brand name reminder and not any other type of promotional item.

In a Code of Conduct complaint, a company argued that a tissue box which had promotional claims and the product information printed upon it was an item of printed promotional material rather than a brand name reminder and was therefore in breach of the Code. As this complaint was brought before amendments to the Code adopted in December 2002, this item was not found in breach of the Code. However, such items would be in breach of Edition 14 of the Code; tissue boxes are accepted as items used commonly as brand name reminders and should not be used as a printed promotional vehicle. In this complaint, concerns were also expressed that this tissue box containing promotional claims may have been viewed by members of the general public.

The section provides that brand name reminders must contain the brand name of the product, the Australian Approved Name of the active ingredient and any boxed warning or a statement drawing attention to a boxed warning. Edition 14 of the Code introduces the possibility of including other information on a brand name reminder. It is now possible to include a non-promotional logo, device or graph and/or a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the product. If you choose to include these items on a brand name reminder their inclusion must not be promotional.

It is recommended that as a general guide the value of a brand name reminder should not be greater than approximately **$10.00** per item.

Section 3.7 - Competitions

Section

3.7.1 *Competitions must fulfil all of the following criteria:*

(i) The competition is based entirely on medical knowledge or the acquisition of medical knowledge.
(ii) The prize is directly relevant to the practice of medicine or pharmacy.
(iii) Individual prizes offered are to be of low monetary value or be an item of educational material.

3.7.2 *Entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.*

3.7.3 *The conduct of competitions shall comply in all respects with relevant State and Federal regulations.*

Explanatory Notes

3.7 *The value of prizes permitted to be used in competitions is difficult to define and needs to be assessed on an individual basis. For further explanation regarding the application of this Section pleaser refer to the current edition of the Guidelines to the Code of Conduct.*

Prizes which might be useful in the practice of medicine but are not specific to medicine or pharmacy must not be offered.

Guidelines

To comply with the requirements of this Section it is critical that all questions are a true test of medical knowledge. For example, questions based on the information contained in a product's PI may be appropriate, whereas questions about a company's postal address or telephone number would not satisfy this section, as the Code of Conduct Committee found in one complaint it considered. All questions must satisfy this requirement.

Prizes offered by a competition must be relevant to the practice of medicine or pharmacy. Examples of appropriate prizes might be an item of medical equipment such as a stethoscope or blood pressure monitor. It is suggested the value of an individual prize should be no greater than **$500**.

Medical educational material may also be provided. An example of an appropriate prize may be a recognised authoritative medical text or attendance at a reputable and educationally valuable scientific meeting. Should companies consider offering the latter type of prize, they should take care to ensure the educational event complies with the requirements of Sections 6, 7 and 10.

It would not be appropriate to provide a prize including an international airfare, accommodation expenses and registration to an international educational meeting. However, an economy class flight, a reasonable level of accommodation costs and the registration fee for a domestic educational meeting may be appropriate. If considering offering this type of prize, companies should refer also to Section 6 to make sure the standards discussed in that section can be complied with when offering this type of prize.

Section 3.8 – Gifts/Offers

Section

No items or offers shall be offered or given to healthcare professionals, their families or employees unless they are items or activities sanctioned by the following sections of this Code:-

a) Section 3.3.3 Brand Name Reminders,
b) Section 3.7 Competitions,
c) Section 6 Involvement in Educational Symposia, Congresses and Satellite Meetings
d) Section 7 Sponsorship
e) Section 10.2 Hospitality or
f) Section10.3 Medical Educational Material

Explanatory Notes

3.8 *For further explanation regarding the application of this Section please refer to the current edition of the Guidelines to the Code of Conduct.*

Guidelines

This section recognises the industry's primary role in providing current, accurate and balanced information on its products to health care professionals. It is not the role of the industry to provide health care professionals with gifts or offers. However the Code does recognize that the following items or opportunities are acceptable and are dealt with in the following specific sections of the Code:-

a)	Section 3.3.3	Brand name reminder
b)	Section 3.7	Prize for a complying competition
c)	Sections 6 and 10	The opportunity to participate in educational meetings
d)	Section 7	Complying sponsorship arrangements
e)	Section 10	Items of medical educational material

This section therefore prohibits the provisions of all gifts and offers that do not conform to these sections.

Section 3.9 – The Use of the Internet for Pharmaceutical Information

Section

Medicines Australia supports the right of Companies to use the Internet as a means of providing accurate and scientifically reliable information on medicines in a responsible manner for the benefit of both patients and health care professionals. However, the promotion of products covered by the Code of Conduct to the general public via the Internet would breach Section 9.4 of the Code and various therapeutic goods legislation which stipulate that prescription medicines must not be promoted to the public.

An advertisement is defined as any statement which is intended (directly or indirectly) to promote the use or supply of a medicine. In providing information to members of the general public, companies must ensure that the intent of this action is informational and not promotional. Care needs to be taken by companies to ensure that material published is of the kind that it is reasonable to conclude that no intention of promotion exists.

The following provisions are applicable to information generated for use via Australian Internet sites.

3.9.1 ***Information available to the General Public***

The purpose of this section is to identify how current, accurate and balanced information regarding prescription medicines available in Australia can be provided via this medium to members of the general public. The intent of the provision of this information must be educational and must never be promotional if it can be accessed by members of the general public.

The following information may be provided to members of the general public:-

3.9.1.1 *A brief non-promotional summary of the company's products available in Australia. This information should be current, accurate and balanced and must not be promotional. It must contain information about the product's precautions, adverse reactions, warnings and contraindications and interactions and may contain information about current research or clinical data that would assist members of the general public understand how this product works, its uses and compliance advice.*

All information provided to members of the general public about prescription medicines must be in accord with the product's current Approved Product Information.

3.9.1.2 *A copy of the product's Consumer Medicines Information (CMI). CMIs must appear in their entirety. They must not be amended, abridged or displayed in a promotional manner.*

3.9.1.3 *Reference or linkages to other reputable information sources that provide valuable educational material that would enhance a member of the general public's understanding of a disease area. When making such a reference or linkage a clear screen displaying the following statements must appear before the information can be accessed:-*

- *that the information a reader is about to be referred to may not comply with the Australian regulatory environment and that readers should refer to the CMI for products to fully understand the terms of a product's registration in Australia*
- *that the intent of providing this material is informational and not as advice*
- *any information provided by this source should be discussed with the reader's health care professional and does not replace their advice*

3.9.2 ***Promotion to and the provision of Information to Health Care Professionals***

3.9.2.1 *Promotional material on products covered by this Code must be accessible only to health care professionals.*

3.9.2.2 *Promotional information provided on the Internet to health care professionals must be accessible only via a secure system that is designed to prevent access by members of the general public.*

3.9.2.3 *Any promotional material provided to health care professionals via this medium must comply with the requirements of Sections 1 and 3 of the Code of Conduct.*

3.9.2.4 *Any references or linkages to other reputable information sources must be to sources which provide valuable educational material that would enhance the quality use of medicines in Australia. When making such a reference or linkage a clear screen displaying the following statement must appear before the reference material is accessed:-*

- *the information a reader is about to be referred to may not comply with the Australian regulatory requirements and that further information relevant to the Australian environment is available from the company or via the Approved Product Information,*

3.9.3 ***General***

3.9.3.1 *Where an Internet site includes information regarding a product, the address and identity of the Company should be provided.*

3.9.3.2 *The intended audience should be readily apparent on the site.*

3.9.3.3 *It should be made clear when the reader is leaving the site or being directed to a site that the Company has not developed.*

3.9.3.4 *It is appropriate for Companies to link their sites to the text of the Code of Conduct on the Medicines Australia's website. Such a linkage must not be used to imply that Medicines Australia endorses any part of the content of the Company's site but to provide information to members of the general public and health care professionals on the Code of Conduct and the standards it sets.*

Explanatory Notes

3.9.1.1. *See Guidelines for examples of the application of this Section.*

3.9.1.3 *To determine whether an information source is appropriate companies must thoroughly and regularly review any information source and must be satisfied that it contains valuable educational material that can be readily understood by members of the general public and would enhance their knowledge of products available in Australia.*

3.9.2.3 *Where reference to other information sources or Internet sites are made, Companies must take all reasonable steps to ensure that these information sources and Internet sites are appropriate and will enhance the appropriate prescribing, dispensing and usage of medicines in Australia.*